



2 April 2003

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Hearing Clerk  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: *Prior Notice of Imported Food Under the Public Health  
And Bio-terrorism Preparedness and Response Act of 2002  
(Docket No. 02N-0278)*

Rhodia Food, a Rhodia food ingredients enterprise, is a global business with significant commerce dependent on the flow of goods into the United States from Europe, Canada and Mexico. While we support FDA in its efforts to insure a safe food supply for consumers and certainly congratulate the agency for its rapid development of the proposed rules on Prior Notice of Imported Foods mandated under the Public Health Security and Bio-terrorism Preparedness Act of 2002, we are concerned that the proposed rule does not take into sufficient consideration the "just-in-time" nature of business practice today nor adequately consider and utilize synergistically those significant activities undertaken by the U.S. Customs Service whose goals are precisely the same reduction of risk of bio-terrorism and deal with other related facets of the security net meant to protect U.S. consumers.

In particular, we note that "just-in-time" manufacturing, shipping, and importation are a reality in today's business model and that the proposed Prior Notice language does not adequately reflect this reality. The agency estimates that some 25% of total imports will be negatively affected by this requirement, however, we strongly suggest that the sampling size noted by FDA for determining market impact is too small to adequately model the tremendous volume of imports entering the U.S. annually and encourage the agency to review and update this estimate using statistically significant data points.

As a specific example of the "just-in-time" nature of cross-border commerce, we note that it is not uncommon for Rhodia to receive an order at one of our Canadian facilities located near to the U.S. border, manufacture and import product in less than 24 hours. Such business practices would be prohibited under the proposed rule. Rhodia Food encourages FDA to reconsider the impact on U.S. / Canadian commerce resulting from the pre-notification requirement of submission of the Prior Notice to FDA "no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry," as the current proposed rule would increase cost, decrease

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our ability to supply our customers on time and, in our view, not necessarily result in increased security of the food supply.

In addition, we recognize that FDA has a responsibility to promulgate rules to implement the will of Congress, but we also urge the agency to take advantage of the excellent work already accomplished in both speed and security of imports undertaken by U.S. Customs to streamline and facilitate the accomplishment of FDA goals. Such inter-agency "team work" would go a long way to streamline the process, reduce duplications and increase efficiency.

We, also, urge FDA to take into account that there is a range of bio-terrorism-related risk associated with the importation of food and food ingredients into the U.S. Rhodia strongly urges that FDA rules should take this range of risk, as well as measures already in place to reduce such risks, into account when developing its Prior Notice rule.

In particular, Rhodia recommends that importers shipping highly compliant cargo and participating in CTPAT (Customs-Trade Partnership Against Terror), FAST (Fast and Secure Trade), PAPS (Pre Arrival Processing System) and NCAP/FAST initiatives, using the Automated Commercial System (ACS) and other systems designed specifically to pre-qualify shippers and shipments for entry into the U.S., should be provided a process which allows maximum flexibility relative to the timeframe of notification. Such flexibility would be risk-based, trade-friendly and prudent.

In summary, Rhodia encourages FDA to take full consideration of the potential of an integrated effort between exporters, importers, customs systems and prior notification procedures to insure the safety of our food supply without unduly disrupting systems in place that are facilitating the safe passage of materials across our border today.

Rhodia Food appreciates the opportunity to comment and participate in the development of the Prior Notice rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin O. Gillies", written over a horizontal line.

Kevin O. Gillies  
Director, Regulatory Affairs – NA  
Rhodia Food  
Rhodia Inc.  
KOG/jn:03-019